IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DUSA PHARMACEUTICALS, INC., a New Jersey corporation; and QUEEN'S UNIVERSITY AT KINGSTON, a Canadian academic organization,	:	Civil Action No. 04-12703-NMG
Plaintiffs,	:	
v.	:	**Oral Argument Requested**
NEW ENGLAND COMPOUNDING PHARMACY, INC., a Massachusetts corporation,	:	
Defendant.	:	

PLAINTIFFS' RESPONSE TO DEFENDANT'S CROSS-MOTION FOR PROTECTIVE ORDER AND COSTS

I. INTRODUCTION

Defendant New England Compounding Pharmacy, Inc. ("NECP") has moved for a protective order to keep Plaintiffs from conducting the inspection that is the only way to determine the truth concerning the conditions under which Defendant's product is manufactured. Defendant also opposes Plaintiffs' motion to compel that same inspection.

Defendant counterclaimed against Plaintiffs, alleging, among other things, that Plaintiffs had defamed Defendant by telling customers that Defendant's ALA-containing solution is of questionable quality because it is not made in a facility or under procedures that meet FDA standards. Plaintiffs defend against these counterclaims in part by contending that such statements are true. Thus, the manufacturing conditions at Defendant's location are central to Plaintiffs' defense of the counterclaims. The inspection that Plaintiffs seek is the only way to establish the truth of this matter.

II. ARGUMENT

A. Inspection of Defendant's Facility Is The Only Means Of Fully Determining Whether The Characteristics Of The ALA-Containing Solution May Be Affected By The Facility Conditions.

No means of discovery other than an inspection of Defendant's premises can uncover facts which will enable the court and jury to decide how Defendant's manufacturing conditions may affect the quality, reliability and safety of Defendant's ALA products. Plaintiffs cannot expect that a deposition of NECP will yield anything other than self-serving assurances which cannot be tested or verified. Plaintiffs cannot rely upon any documentary evidence because Defendant refuses to produce relevant documents, or represents that such documents do not exist.[1] Only an inspection will enable Plaintiffs to put the whole truth before the court and jury.[2]

Defendant also suggests that testing a limited number of samples of its ALA-containing solution is sufficient to establish the safety, identity, strength, quality and purity characteristics of the entirety of its ALA-containing solutions. Plaintiffs have offered proof in the form of the

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[1] Defendant argues that "through deposition or document request DUSA can obtain information about the companies from which DUSA purchases the elements used in its compounding process . . . ." NECP's Opposition to DUSA's Motion to Compel Inspection and Cross-Motion for Protective Order and Costs ("NECP's Opposition"), at 7. However, Defendant has refused to provide materials in response to requests for documents evidencing, among other things, the identity and quality of the components, containers, closures or labeling of its ALA-containing solution. See Exhibit A, NECP's Response and Objections to Plaintiff's First Request for Production of Documents ("Responses to Document Requests"), at ¶ 46. Defendant has also taken the position that it has no documents evidencing a number of essential areas that might shed light on the impact of the conditions at the NECP facility. Defendant claims to have no documents relating to controls, tests or examinations conducted on samples of the ALA-containing product; the procedures or practices designed to prevent contamination within the facility; its methods of reprocessing batches of ALA that do not conform to established standards; procedures for ensuring correct labeling and packaging and whether labeling and packaging has been applied properly; whether batches of Defendant's ALA-containing solution are uniform; whether the manufacturing, processing, packaging and holding of each ALA batch is accomplished pursuant to Defendant's own established procedures; and what becomes of ALA that has been subjected to improper storage conditions. Id., at ¶¶ 35, 36, 37, 39; ¶¶ 48, 49. Regardless, while such documents might be helpful in establishing the conditions at Defendant's facility (should they be produced or be found to exist), they cannot substitute for an inspection.

[2] Moreover, the inspection cannot be limited to the area in which Defendant's ALA-containing solution is compounded. Improper conditions in any of the areas through which the ALA-containing solution or its components pass may affect the characteristics of Defendant's ALA product.

affidavit of expert David L. Chesney that the characteristics of a drug product should be verified by examining the processes, procedures and conditions under which the product is produced. This is the only means of assuring that a test result on a single sample is consistent with the rest of the batch produced, and other batches not tested. See Affidavit of David L. Chesney, attached as Exhibit C to Plaintiffs' Memorandum of Law in Support of Motion to Compel ("Plaintiffs' Memorandum"), at ¶ 11. Inspection, rather than testing, is even more important in this case where Defendant has represented that it has no documents establishing the uniformity of its batches of ALA-containing solution. See Responses to Document Requests, at ¶ 48.

B. The Inspection Sought By Plaintiffs Is Of A Type Expressly Contemplated Under The Law.

Defendant's authority for the principles governing entries upon land establishes that the inspection Plaintiffs seek – an examination of the conditions of the Defendant's premises – is specifically contemplated under the law. See Belcher v. Bassett Furniture Indus., Inc., 588 F.2d 904, 910 (4th Cir. 1978) ("[m]ost cases involving on-site inspections concern a given object on the premises which is the subject matter of the action, as, for example, a particular machine in a personal injury or patent infringement case."). Courts disallowed only those entries that are, in practice, depositions or document inspections. See, e.g., Belcher, 588 F.2d at 909-910 (a five day inspection comprised of "roaming through the plants addressing random inquiries to employees . . . lends credence to the suspicion that interrogations are intended as substitutes for depositions."); Ares-Serono, Inc. v. Organon Inter'l B.V., 160 F.R.D. 1, 6 (D. Mass. 1994) (document requests were the proper method of discovery where party sought an entry upon land for the purpose of inspecting documents).

In this case, neither deposition nor document request can substitute for Plaintiffs' inspection, and Plaintiffs do not seek to examine Defendant's premises for the purposes of either

taking unsworn testimony or looking at documents. In our case, Plaintiffs have already agreed that the inspectors will not photograph, videotape or speak with Defendant's employees. See Plaintiffs' August 19, 2005 correspondence, Exhibit 6 to Affidavit of Valerie Brand Pipano, attached as Exhibit B, to the Plaintiffs' Memorandum. The inspectors will not examine the contents of documents at the time of entry and inspection. Id. Still, Defendant will not permit the inspection to go forward. [3]

III. CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that this Court enter an Order compelling Defendant to permit an entry and inspection of its facility and operations within seven (7) days of the date of the Order. Such inspection shall include all relevant areas of Defendant's premises likely to lead to the discovery of admissible evidence, shall not be limited to Defendant's compounding "laboratory," and shall include the inspection of all containers and cabinets contained therein.

Respectfully submitted,

DUSA PHARMACEUTICALS, INC. and
QUEEN'S UNIVERSITY AT KINGSTON

By their attorneys,

/s/ Mona M. Patel
Edward Naughton (BBO #600059)
Mona M. Patel (BBO #641007)
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[3] Plaintiffs also consented to hold the entry on a date convenient for Defendant, and after business hours. Plaintiffs agreed to an inspection team of only five necessary persons, even declining Defendant's offer to include Plaintiffs' corporate representative. See Cox v. E.I. DuPont de Nemours and Co., 38 F.R.D. 396, 398 (D. S.C. 1965) (permitting entry but limiting the number of inspectors); Martin v. Reynolds Metals Corp., 297 F.2d 49, 57 (9th Cir. 1961) (limiting to ten the number of inspectors and requiring that the parties set specific dates and times for entry).

William J. McNichol, Jr. (*pro hac vice*)
Maryellen Feehery (*pro hac vice*)
Valerie Brand Pipano (*pro hac vice*)
Tamara J. Yorita (*pro hac vice*)
Reed Smith LLP
1650 Market Street
Philadelphia, PA 19103
(215) 851-8100 (phone)
(215) 851-1420 (fax)

Dated: September 30, 2005

CERTIFICATE OF SERVICE

I, Mona M. Patel, hereby certify that on this 30th day of September, 2005, I caused the within Plaintiffs' Response To Defendant's Cross-Motion For Protective Order And Costs to be served upon the Defendant in this action by causing a copy thereof to be delivered by electronic filing, electronic mail, facsimile and hand to Defendant's counsel of record, Daniel Rabinovitz, Esq., Menard, Murphy & Walsh LLP, 60 State Street, Boston, Massachusetts 02109.

/s/ Mona M. Patel

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DUSA PHARMACEUTICALS, INC. and QUEEN'S UNIVERSITY AT KINGSTON, Plaintiffs, v. NEW ENGLAND COMPOUNDING PHARMACY, INC. Defendant.	Civil Action No. 04-12703 NMG

DEFENDANT NEW ENGLAND COMPOUNDING PHARMACY, INC.'S RESPONSE AND OBJECTIONS TO PLAINTIFF'S FIRST REQUEST FOR PRODUCTION OF DOCUMENTS

Defendant, Plaintiff-in-counterclaim, New England Compounding Pharmacy Inc., Inc. ("New England Compounding Pharmacy Inc.") responds and objects to DUSA.'s ("DUSA" or Plaintiff") First Request for Production of Documents as follows:

GENERAL OBJECTIONS

New England Compounding Pharmacy Inc. objects to Plaintiff's definitions and instructions to the extent the definitions and instructions exceed the requirements set forth in Rules 26 and 34 of the Federal Rules of Civil Procedure. New England Compounding Pharmacy Inc. also objects to Plaintiff's requests to the extent they:

A. Are unreasonably cumulative and duplicative of other requests or seek documents obtainable from some other source that is more convenient, less burdensome or less expensive;

B. Call for an unduly burdensome and expensive response, taking into account the needs of the case, the amount in controversy, limitations on the party's resources, and the importance of the issues at stake;

C. Seek discovery of attorney work product or trial preparation materials without the required showing that Plaintiffs have a substantial need for them and that they are unable, without undue hardship, to obtain the substantial equivalent of the requested information by other means;

D. Seek materials protected by the attorney-client privilege;

E. Seek disclosure of the mental impressions, conclusions, or legal theories of New England Compounding Pharmacy Inc.' attorneys;

F. Are overly broad and seek documents that are irrelevant to the subject matter of this action and are not reasonably calculated to lead to the discovery of evidence that would be admissible at trial;

G. Seek documents that contain confidential, proprietary information or trade secrets; or

H. Are vague and/or ambiguous.

Subject to and without waiving these objections, New England Compounding Pharmacy Inc. responds to Plaintiff's First Request for Production of Documents as follows:

1. All documents evidencing, referring to or relating to the validity or enforceability of U.S. Patent Nos. 5,955,490 or 6,710,066, including any and all prior art for U.S. Patent Nos. 5,955,490 or 6,710,066 known to the Defendant and/or its counsel.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, C, D, E and F. Subject to and without waiving these objections, defendant does not possess any documents described in this request.

2. All documents evidencing, referring to, or relating to the non-infringement of U.S. Patent Nos. 5,955,490 or 6,710,066 by Defendant's sale of ALA for the treatment of acne or actinic keratosis.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, C, D, E and F. Subject to and without waiving these objections, defendant does not possess any documents described in this request.

3. All documents evidencing, referring to, or relating to any test, analysis, or study made by or on behalf of the Defendant of the clinical effectiveness or mode of action of aminolevulinic acid.

Response:

Defendant does not possess any documents described in this request.

4. All documents evidencing, referring to or relating to any advertising and/or promotional materials by or on behalf of the Defendant of ALA, including but not limited to all advertisements sent by facsimile (including drafts thereof), and lists of recipients and/or potential recipients of adverting and/or promotional materials.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, C, D, E and F, G, H. Subject to and without waiving these objections, New England Compounding Pharmacy agrees to

make available documents responsive to this request.

5. All documents evidencing, referring to or relating to any sales made by or on behalf of the Defendant of ALA.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, and F, G, H.

6. All documents evidencing, referring to, relating to and/or identifying Defendant's ALA customers (whether intermediary or distributors) and/or potential customers (whether or not a sale has been consummated), including but not limited to customer lists.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, and F, G, H.

7. All documents in Defendant's custody, control or possession (including the custody, control or possession of Defendant's employees) evidencing, referring to, relating to and/or purporting to identify DUSA customers and/or potential customers.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, and F, G, H.

8. All documents evidencing, referring to or relating to communications by and between Defendant and physician-customers, physicians and/or customers related to the purchase or potential purchase of the ALA, including but not limited to correspondence, inquiries and/or prescriptions.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, and F, G, H.

9. All documents evidencing, referring to or relating to any action or statement made by or on behalf of one or both Plaintiffs which have an anticompetitive effect.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

10. All documents evidencing, referring to or relating to any action or statement made by or on behalf of one or both Plaintiffs which support an affirmative defense of unclean hands.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

11. All documents evidencing, referring to or relating to Defendant's contention that the December 27, 2004 press release contained false and/or misleading remarks.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

12. All documents evidencing, referring to or relating to Defendant's contention that the January 31, 2005 press release contained false and/or misleading remarks.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

13. All documents evidencing, referring to or relating to Defendant's contention that

one or both Plaintiffs made false and/or misleading statements to Defendant's customers, potential customers and/or third parties.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

14. All documents evidencing, referring to or relating to any action or statement made by or on behalf of one or both Plaintiffs in February-March 2005 at South Shore Skin Care Center.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

15. All documents evidencing, referring to or relating to any action or statement made by or on behalf of one or both Plaintiffs in the winter of 2005 to a physician as alleged in the Complaint.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

16. All documents evidencing, referring to or relating to Defendant's contention that one or both Plaintiffs made false and/or misleading statements to state and/or federal governing bodies disparaging Defendant's business and the quality of Defendant's products.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

17. All documents evidencing, referring to or relating to any action or statement made by

or on behalf of one or both Plaintiffs which are false, misleading, disparaging, or defaming Defendant, its business or its aminolevulinic acid.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

18. All documents evidencing, referring to or relating to any action or statement made by or on behalf of the Defendant which actively induce infringement of U.S. Patent Nos. 5,955,490 or 6,710,066.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

19. All documents evidencing, referring to or relating to the regulation of aminolevulinic acid by the U.S. FDA.

Response:

Defendant does not possess any documents described in this request.

20. All documents evidencing, referring to or relating to any search of the prior art to U.S. Patent Nos. 5,955,490 or 6,710,066.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, C, D, E and F. Subject to and without waiving these objections, defendant does not possess any documents described in this request.

21. All documents evidencing, referring to or relating to invalidity and/or non-infringement, including but not limited to non-infringement opinions.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, C, D, E and F. Subject to and without waiving these objections, defendant does not possess any documents described in this request.

22. All documents evidencing, referring to or relating to Defendant's contention that one or both Plaintiffs tortiously interfered with business relationships between Defendant and any physician-customers, physicians and/or customers.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

23. All documents evidencing, referring to or relating to Defendant's contention that actions of one or both Plaintiffs constitute unfair and deceptive actions within the meaning of Mass. G.L. Chapter 93A, § 11.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

24. All documents evidencing, referring to or relating to Defendant's contention that one or both Plaintiffs made false and/or deceptive representations to customers, such as false and/or misleading remarks disparaging the quality and source of Defendant's compounds comprising ALA solution.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

25. All documents evidencing, referring to or relating to Defendant's contention that representations of one or both Plaintiffs regarding Defendant and/or Defendant's ALA solution deceived a significant portion of the consuming public.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

26. All documents evidencing, referring to, relating to or identifying Defendant's employees and/or other persons involved in the manufacturing, quality control, storage, and/or shipping of the ALA and any components thereto.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

27. All documents evidencing, referring to or relating to Defendant's standard operating procedures with respect to the ALA. This request also includes all documents and/or records maintained pursuant to these procedures, documenting compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, and F, G, H.

To the extent this request calls for material required by the FDA of a manufacturer, New England Compounding Pharmacy objects to this request on the grounds that New England Compounding Pharmacy is not a manufacturer and as such is not required to maintain the documents described in this request. Thus, New England Compounding Pharmacy does not possess most of the documents described in this request. Subject to the foregoing, and without waiving the objections set forth above, New England Compounding Pharmacy agrees to make available whatever responsive documents New England Compounding Pharmacy has in its possession.

28. All documents evidencing, referring to or relating to Defendant's procedures for assigning responsibility for sanitation, including but not limited to cleaning schedules, methods, equipment and/or materials to be used in cleaning the building and facilities. This request also includes all documents and/or records maintained pursuant to these procedures, documenting compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, and F, G, H.

To the extent this request calls for material required by the FDA of a manufacturer, New England Compounding Pharmacy objects to this request on the grounds that New England Compounding Pharmacy is not a manufacturer and as such is not required to maintain the documents described in this request. Thus, New England Compounding Pharmacy does not possess most of the documents described in this request. Subject to the foregoing, and without waiving the objections set forth above, New England Compounding Pharmacy agrees to make available whatever responsive documents New England Compounding Pharmacy has in its possession

29. All documents evidencing, referring to or relating to Defendant's procedures for the use of rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents, including but not limited to procedures designed to prevent the contamination of equipment, components, product containers, closures, packaging, labeling materials, or the ALA product. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, and F, G, H.
To the extent this request calls for material required by the FDA of a manufacturer, New England Compounding Pharmacy objects to this request on the grounds that New England Compounding Pharmacy is not a manufacturer and as such is not required to maintain the documents described in this request. Thus, New England Compounding Pharmacy does not possess most of the documents described in this request. Subject to the foregoing, and without waiving the objections set forth above, New England Compounding Pharmacy agrees to make available whatever responsive documents New England Compounding Pharmacy has in its possession.

30. All documents evidencing, referring to or relating to Defendant's procedures for cleaning and maintenancing equipment, including utensils, used in the manufacture, processing, packing or holding of ALA, including but not limited to procedures for (a) assignment of responsibility for cleaning and maintaining equipment; (b) maintenance and cleaning schedules, including, where appropriate, sanitizing schedules; (c) a description of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and

reassembling equipment as necessary to assure proper cleaning and maintenance; (d) removal or obliteration of previous batch identification; (e) protection of clean equipment from contamination prior to use; and (f) inspection of equipment for cleanliness. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, and F, G, H.
To the extent this request calls for material required by the FDA of a manufacturer, New England Compounding Pharmacy objects to this request on the grounds that New England Compounding Pharmacy is not a manufacturer and as such is not required to maintain the documents described in this request. Thus, New England Compounding Pharmacy does not possess most of the documents described in this request. Subject to the foregoing, and without waiving the objections set forth above, New England Compounding Pharmacy agrees to make available whatever responsive documents New England Compounding Pharmacy has in its possession.

31. All documents evidencing, referring to or relating to Defendant's procedures for use of automatic, mechanical, electronic equipment and/or other types of equipment, including computers, or related systems used in the manufacture, processing, packing, and holding of your ALA, including but not limited to documents relating to: (a) calibration and/or inspection to assure proper performance; (b) controls over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel; and (c)

procedures to ensure that input to and output from the computer or related system of formulas or other records or data are checked for accuracy. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, and F, G, H.
To the extent this request calls for material required by the FDA of a manufacturer, New England Compounding Pharmacy objects to this request on the grounds that New England Compounding Pharmacy is not a manufacturer and as such is not required to maintain the documents described in this request. Thus, New England Compounding Pharmacy does not possess most of the documents described in this request. Subject to the foregoing, and without waiving the objections set forth above, New England Compounding Pharmacy agrees to make available whatever responsive documents New England Compounding Pharmacy has in its possession.

32. All documents evidencing, referring to or relating to Defendant's procedures for ensuring that back up data relating to the manufacture, processing, packing and holding of ALA is complete and is secure from alteration, inadvertent erasures or loss, such procedures including but not limited to the use of backup files of data entered into computers or related systems, written records, hard copies, duplicates, tapes, microfilm and/ or alternate means of data storage. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

Defendant does not possess any documents described in this request.

33. All documents evidencing, referring to or relating to Defendant's procedures for the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures for ALA. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, and F, G, H.
To the extent this request calls for material required by the FDA of a manufacturer, New England Compounding Pharmacy objects to this request on the grounds that New England Compounding Pharmacy is not a manufacturer and as such is not required to maintain the documents described in this request. Thus, New England Compounding Pharmacy does not possess most of the documents described in this request. Subject to the foregoing, and without waiving the objections set forth above, New England Compounding Pharmacy agrees to make available whatever responsive documents New England Compounding Pharmacy has in its possession.

34. All documents evidencing, referring to or relating to Defendant's procedures for production and process control designed to assure that the ALA, and/or any components of the ALA, has the identity, strength, quality, and purity you believe purport or represent it to possess, including but not limited to procedures for recording and justifying deviations from established procedures. This request also includes all documents and/or records maintained pursuant to these

procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, and F, G, H.

To the extent this request calls for material required by the FDA of a manufacturer, New England Compounding Pharmacy objects to this request on the grounds that New England Compounding Pharmacy is not a manufacturer and as such is not required to maintain the documents described in this request. Thus, New England Compounding Pharmacy does not possess most of the documents described in this request. Subject to the foregoing, and without waiving the objections set forth above, New England Compounding Pharmacy agrees to make available whatever responsive documents New England Compounding Pharmacy has in its possession.

35. All documents evidencing, referring to or relating to Defendant's procedures that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch of ALA to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product, including but not limited to procedures with respect to (a) weight variation; (b) disintegration time; (c) adequacy of mixing to assure uniformity and homogeneity; (d) dissolution time and rate; (e) clarity, completeness, or pH of solutions; and (e) procedures for identifying and controlling rejected in-process materials. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

Defendant does not possess any documents described in this request.

36. All documents evidencing, referring to or relating to Defendant's procedures designed to prevent objectionable microorganisms in your ALA product. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

Defendant does not possess any documents described in this request.

37. All documents evidencing, referring to or relating to Defendant's procedures for prescribing a system for reprocessing batches of ALA that do not conform to standards or specifications and the steps to be taken to insure that the reprocessed batches will conform with all established standards, specifications, and characteristics. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

Defendant does not possess any documents described in this request.

38. All documents evidencing, referring to or relating to Defendant's procedures for the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials for your ALA. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with

these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

39. All documents evidencing, referring to or relating to Defendant's procedures to assure that correct labels, labeling, and packaging materials are used for your ALA, and/or the results of inspection to ensure the correct labels, labeling and packaging materials. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

Defendant does not possess any documents described in this request.

40. All documents evidencing, referring to or relating to Defendant's procedures for the warehousing of your ALA, including but not limited to procedures for: (a) a quarantine of your ALA before release by the quality control unit; and (b) storage of your ALA under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity are not affected. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

41. All documents evidencing, referring to or relating to Defendant's procedures

describing the distribution of your ALA, including but not limited to: (a) procedures for the order for distribution of batches of ALA; and (b) a system by which the distribution of each lot of ALA can be readily determined to facilitate its recall if necessary. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

42. All documents evidencing, referring to or relating to Defendant's procedures for the establishment of any specifications, standards, sampling plans, test procedures, and/or other laboratory control mechanisms. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

43. All documents evidencing, referring to or relating to Defendant's procedures for enacting sampling and/or testing plans for determinations of conformance to final specifications for your ALA, including specifications for the identity and strength of each active ingredient, prior to release. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

44. All documents evidencing, referring to or relating to Defendant's testing program designed to assess the stability characteristics your ALA. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

45. All documents evidencing, referring to or relating to Defendant's procedures for record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments). This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

46. All documents evidencing, referring to or relating to: (a) the identity and quantity of each shipment of each lot of components, containers, closures, and labeling for ALA, the name of the supplier; the supplier's lot number(s) if known, the receiving codes, and the date of receipt; (b) Defendant's examination upon receipt of each container or grouping of containers of components, ALA containers and closures for appropriate labeling as to contents, container damage or broken seals, and/or contamination; and/or (c) Defendant's examination or testing of labeling and/or

packaging materials for your ALA.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, and F, G, H.

47. All documents evidencing, referring to or relating to the disposition of rejected ALA components, containers, closures, and labeling.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

48. All documents evidencing, referring to or relating to uniformity from batch to batch of your ALA, including but not limited to master production and control records for each drug product.

Response:

Defendant does not possess any documents described in this request.

49. All documents referring to, relating to or evidencing that each significant step in the manufacture, processing, packing, or holding of each ALA batch was accomplished pursuant to Defendant's procedures, including but not limited to documents reflecting dates, identity of individual major equipment and lines used, specific identification of each batch of component or in-process material used, weights and measures of components used in the course of processing, in-process and laboratory control results, inspection of the packaging and labeling area before and after use, a statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing, labeling control records, including specimens or copies of all

labeling used, description of drug product containers and closures, any sampling performed, identification of the persons performing and directly supervising or checking each significant step in the operation.

Response:

Defendant does not possess any documents described in this request.

50. All documents evidencing, referring to or relating to Defendant's procedures for the handling of all written and oral complaints regarding your ALA, including but not limited to provisions for review of any complaint involving the possible failure of the ALA to meet any of its specifications and provisions for a determination as to the need for an investigation, and provisions to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to any governing governmental body. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

51. All documents evidencing, referring to or relating to each complaint made to Defendants related to your ALA, be it written or oral, including but not limited to any findings, investigation and/or follow-up thereto, or determination that an investigation was not to be undertaken.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

52. All documents evidencing, referring to or relating to each returned ALA product, including but not limited to any findings, investigation and/or follow-up thereto, or determination that an investigation was not to be undertaken.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

53. All documents evidencing, referring to or relating to Defendant's procedures for the holding, testing, and/or reprocessing of returned drug products. This request also includes all documents and/or records maintained pursuant to these procedures, refer or relate to compliance and/or noncompliance with these procedures, and/or relate to conduct undertaken as a result of these procedures.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

54. All documents evidencing, referring to or relating to ALA that had been subjected to improper storage conditions, including but not limited to extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment, that Defendant has salvaged and put into, or returned to, the marketplace.

Response:

Defendant does not possess any documents described in this request.

55. All documents evidencing, referring to or relating to the shipment of each batch of ALA, including but not limited to the receiver of the shipment and the date on which the shipment was shipped.

Response:

New England Compounding Pharmacy hereby incorporates by reference the objections previously set forth in its General Objections above, particularly Objections A, B, and F, G, H

56. All documents evidencing, referring to or relating to the claims of damages asserted by Defendant.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request. In addition, New England Compounding Pharmacy reserves the right to supplement this response based on future acts committed by DUSA.

57. All Defendant's ALA container(s) as provided to customers, and all components thereto, including but not limited to applicator(s), package insert(s), packaging, label(s), and label insert(s).

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request

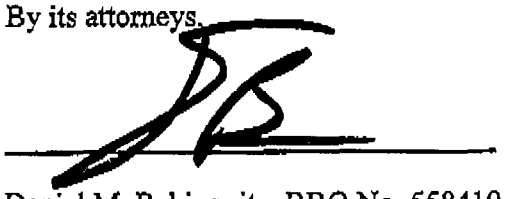
58. All documents referred to by Defendant in its Initial Disclosures.

Response:

New England Compounding Pharmacy agrees to make available documents responsive to this request.

New England Compounding Pharmacy, Inc.

By its attorneys,



Daniel M. Rabinovitz, BBO No. 558419

Menard, Murphy & Walsh LLP

60 State Street - 34th Floor

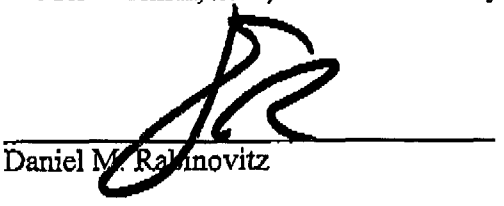
Boston, Massachusetts 02109

(617) 832-2500

Dated: September 23, 2005

CERTIFICATE OF SERVICE

I, Daniel M. Rabinovitz, hereby certify that on this 23rd day of September, 2005, I caused a copy of this Response to Plaintiff's First Request for Production of Documents to be served by facsimile transmission, addressed to Mona M. Patel, Esquire of Holland & Knight, 10 St. James Avenue, Boston, MA 02116 and Valerie Brand Pipano of Reed Smith, LLP, 2500 One Liberty Place, 1650 Market Street, Philadelphia, PA 19103.



Daniel M. Rabinovitz